



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 22, 2020

Don Jacques
EHS & Regulatory Affairs Manager
Bio-Cide International
2650 Venture Dr.
Norman OK 73069

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Purogene
EPA Registration Number: 9804-5
Application Date: Oct 5, 2020
Decision Number: 563404

Dear Mr. Jacques:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are large non-enveloped, and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Poliovirus Type 1 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

Purogene®

ACCEPTED

09/22/2020

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 9804-5

CHLORINE DIOXIDE

For Commercial and Institutional Use

Deodorizer-Sanitizer-Disinfectant

FUNGICIDAL-BACTERICIDAL-VIRUCIDAL-TUBERCULOCIDAL

Active Ingredient:
Chlorine Dioxide.....2.00%
Other Ingredients.....98.00%
Total.....100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

STORE IN COOL DARK PLACE - KEEP FROM FREEZING

**Bio-Cide International, Inc.
2650 Venture Drive
Norman, Oklahoma 73069**

*EPA Reg. No. 9804-5
Est. No. 9804-OK-1*

Net Contents: ___ Quart ___ Gallon ___ 5 Gallons ___ 30 Gallons ___ 55 Gallons

PROPER ACTIVATION OF PUROGENE®

MEASURE out the desired volume of PUROGENE® concentrate into a clean vessel in a well-ventilated area. ADD the required amount of activator acid, stir and allow to dissolve for five minutes for citric acid or two minutes for phosphoric acid. Avoid breathing any fumes that may be produced. After appropriate activation time, DILUTE with clean water to your desired final concentration.

<u>CONCENTRATION</u>		<u>OUNCES PER 5 GALLONS</u>		<u>CITRIC ACID</u>
5	ppm	0.16	fl. oz./5 gallon	0.5g
10	ppm	0.32	fl. oz./5 gallon	1.0g
20	ppm	0.64	fl. oz./5gallon	2.0g
40	ppm	1.28	fl. oz./5gallon	4.0g
50	ppm	1.60	fl. oz./5gallon	5.0g
100	ppm	3.20	fl. oz./5gallon	10.0g
200	ppm	6.40	fl. oz./5gallon	20.0g
500	ppm	16.00	fl. oz./5gallon	50.0g

<u>CONCENTRATION</u>		<u>OUNCES PER 5 GALLONS</u>		<u>33% PHOSPHORIC ACID</u>
5	ppm	0.16	fl. oz./5 gallon	0.025 fl.oz.
50	ppm	1.60	fl. oz./5gallon	0.25 fl.oz.
100	ppm	3.20	fl. oz./5gallon	0.5 fl.oz.
500	ppm	16.00	fl. oz./5gallon	2.5 fl.oz.

Proper Dilution of Purogene®

Parts per
Million

5 ppm	0.032	fl. oz per gallon	or	0.25 ml per liter
10 ppm	0.064	fl. oz. per gallon	or	0.5 ml per liter
20 ppm	0.128	fl. oz. per gallon	or	1.0 ml per liter
40 ppm	0.256	fl. oz. per gallon	or	2.0 ml per liter
50 ppm	0.320	fl. oz. per gallon	or	2.5 ml per liter
100 ppm	0.640	fl. oz. per gallon	or	5.0 ml per liter
200 ppm	1.280	fl. oz. per gallon	or	10.0 ml per liter
400 ppm	2.560	fl. oz. per gallon	or	20.0 ml per liter
500 ppm	3.200	fl. oz. per gallon	or	25.0 ml per liter

Alternative Activation

The active biocidal component of Purogene® system is free chlorine dioxide. Unactivated Purogene® in the neutral to mildly alkaline pH ranges is bacteriostatic. For higher level microbial control, such as disinfection and sanitation, activation of Purogene® is required to generate free chlorine dioxide. The use of citric acid as an activator is specified in most Purogene® applications. Alternatives to citric acid for activation include generally regarded as safe (GRAS) organic acids, such as acetic acid, and inorganic acids such as phosphoric, hydrochloric, and sulfuric acids. Activation equivalent to that of citric acid may be achieved by adjusting the Purogene® solution to pH 2-3 with an alternative acid. The activated Purogene® is then diluted to the required used concentration in accordance with label instructions. For food processing applications only food grade activator acids may be used. Bio-Cide International, Inc. or your Purogene® distributor can guide you in proper activation techniques.

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

FOR USE IN WATER AND ICE

1. In potable water for the improvement of taste and odor and for inhibiting bacteria growth: 1.0-5.0 ppm.
2. In ice, as a sanitizer, made from potable water for use in drinking glasses and cups: 20 ppm unactivated.
3. In individual ice flaking and cubing machines to inhibit bacterial slime buildup: 20 ppm unactivated.

For Commercial Use:

1. In ice plants to inhibit bacteria and slime buildup on ice-making equipment: 40 ppm unactivated.
2. As a bacteriostat in ice: 40 ppm unactivated.

For Hospital & Institutional Use:

1. As a sanitizer in ice, made from potable water, while in ice storage equipment: 20 ppm unactivated.

FOR SANITIZING POTABLE WATER STORAGE TANKS

1. Drain tank; remove sediments.
2. Fill tank with sanitizing solution. (See ACTIVATION AND DILUTION PROCEDURES below)
3. Drain small amount of sanitizer solution from all outlets, then add makeup solution to tank.
4. Allow sanitizing solution to stand for specified amount of time. (See below)
5. Drain and flush system with potable water.
6. Fill tank with potable water or water treated at 1 to 5 ppm.

ACTIVATION AND DILUTION PROCEDURES FOR SANITIZING POTABLE WATER STORAGE TANKS.

5-Minute Procedure: (100 ppm available ClO₂) For each 50 gallons of tank capacity, mix 32 fl. oz. of Purogene with 1/2 cup (4 oz.) citric acid or equivalent in a plastic container. Let mixture stand five (5) minutes. Dilute activated concentrate with two (2) gallons of potable water. Pour solution into tank and fill with water. Allow active sanitizing solution to stand in tank for at least five minutes.

1-Hour Procedure: (50 ppm available ClO₂) For each 50 gallons of tank capacity, mix 16 fl. oz. of Purogene with 1/4 cup (2 oz.) citric acid or equivalent in a plastic container. Let mixture stand five (5) minutes. Dilute activated concentrate with two (2) gallons of potable water. Pour solution into tank and fill with water. Allow active sanitizing solution to stand in tank for one hour.

DISINFECTION

To disinfect non-porous, hard surfaces in aircraft, recreational vehicles, boats and other conveyances, such as door handles, arm rests, tray tables, window shades and lavatory surfaces.

- i) Clean all surfaces thoroughly prior to disinfection.
- ii) Preparation of active disinfecting solution: Prepare an activated working solution containing 500 ppm available chlorine dioxide according to the activation chart.
- iii) To apply: Activated solutions may be sprayed, wiped or sponged onto surfaces to be disinfected. All surfaces must be thoroughly wetted for at least ten (10) minutes. When spraying disinfectant solutions, use an appropriate spraying device. Active solutions may be irritating when breathed, therefore, always use an applicable NIOSH approved respirator appropriate for chlorine dioxide when spraying these solutions. After application, allow to air dry. Treat as required. Always apply freshly made solutions. Never reuse activated solutions.

TO CONTROL BUILD-UP OF SLIME AND ODOR CAUSING BACTERIA AND ENHANCE THE TASTE OF STORED POTABLE WATER.

- i) Prior to treatment of potable water, thoroughly clean and disinfect the water storage system to ensure a sanitary condition. Thoroughly rinse with clean, potable water.
- ii) Potable water should be treated at a rate of one (1) fl. oz. Purogene® per 30 gallons potable water (5 ppm available ClO₂) and may be injected or batch treated.
- iii) Water storage tank should be sufficiently sealed to prevent outside contamination and direct sunlight.
- iv) Using a Bio-Cide test kit, confirm the chemical level to be 5 ppm and check to see this level does not fall below 1 ppm

TO CONTROL THE SPREAD OF LATE BLIGHT, SOFT ROT, DRY ROT, SILVER SCURF, RING ROT, PINK ROT, BLACK SCURF AND OTHER TUBER DISEASE CAUSING ORGANISMS IN POTATO STORAGE SHEDS:

Activation of Purogene

Prior to dilution, the product concentrate must be activated by addition of a food grade acid in order to generate free chlorine dioxide. See below for directions on activation.

FOR THE TREATMENT OF WATER USED TO SPRAY OR RINSE POTATOES PRIOR TO STORAGE.

- 1) Activation:
For piling applications, activate 5 gallons of Purogene with 25 oz. (1.6 lbs.) of citric acid (99% fine granular), or 7.5 fl. oz. of 75% phosphoric acid. Wait 30 minutes.
- 2) Dilution:
Dilute activated concentrate to 400 ppm.
5 gallons of Purogene + 250 gallons of water = 400 ppm solution.
- 3) Apply 400 ppm solution directly on tubers going into storage using any appropriate means such as spraying or misting. For small volume applications, refer to the Technical Data Sheet.

FOR THE TREATMENT OF HUMIDIFICATION WATER TO CONTROL TUBER DISEASE CAUSING ORGANISMS ON STORED POTATOES.

1) Activation:

For humidification applications, activate 5 gallons of Purogene with 7.5 oz. (0.47 lbs.) of citric acid (99% fine granular), or 2.5 fl. oz. of 75% phosphoric acid. Wait 30 minutes.

2) Dilution:

Dilute activated concentrate to 200 ppm.

5 gallons of Purogene + 500 gallons of water = 200 ppm solution.

3) For continual treatment of high-risk storage, an initial treatment up to 200 ppm may be added to the humidification as either a mist into the air stream, or as a fog directly into the plenums.

4) For the periodic treatment of storage with unknown risk, a treatment up to 200 ppm may be applied as either a mist into the air stream, or as a fog directly into the plenums.

4) To reduce the amount of water added to the storage during fogging treatments, concentrations of up to 400 ppm of activated product may be applied to the air streams.

Owners/operators of potato storage facilities must ensure adequate protection of workers and handlers, according to the following guidance.

PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) that must be worn during mixer/loader task associated with pre-storage applications of Purogene includes: chemical-resistant gloves, goggles/face shield, and NIOSH approved canister/cartridge respirator rated for chlorine/acid gas vapors or specified for chlorine dioxide.

Chemical resistant gloves must be worn for all other handler activities in which the worker is placed in direct contact with either the wet treated potatoes (e.g., during inspection/disease monitoring in the storage shed) or the humidification water system/process water tank (during equipment cleaning/maintenance.)

RESTRICTIONS

People must vacate the premises during fogging treatment; a one-hour restricted entry interval (REI) is required.

Do not allow unprotected workers in the area to be exposed above the permissible exposure limit (PEL) of 0.1 ppm for an 8 hour time weighted average (TWA), or 0.3 ppm for any 15 minute short term exposure limit (STEL).

Avoid storing product under conditions in which it could evaporate to a crystalline salt.

All potatoes treated must have a potable rinse applied before further processing. Fruits and vegetables treated with chlorine dioxide must be blanched, cooked, or canned before consumption or distribution in commerce. Avoid accidental contact with acids, chlorine compounds, hypochlorite (bleach), sulfur and sulfite compounds, phosphorus, organic solvents, and combustible/flammable materials. Exposure to acids or chlorine compounds can produce uncontrolled generation of chlorine dioxide.

Do not allow chlorine dioxide to accumulate in confined spaces.

Waste water containing residual chlorine dioxide and its breakdown products like chlorite, chlorate, or chloride ions will not be transferred to public water ways but kept in an open pond or reservoir to go through aeration (which helps in the dissociation of chlorine dioxide) in the confines of the treatment facility and only discarded after the levels of these pesticides are equal to or lower than the ones recommended by EPA's Office of Water.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Product Storage: Store in a cool, dry, well-ventilated location away from acids, chlorine and chlorine compounds, hypochlorites (bleach), organic solvents, sulfur and sulfite compounds, phosphorus, combustible/ flammable materials, and direct sunlight. Keep containers tightly closed when not in use and open carefully to prevent spillage. Storage on wooden floors and pallets is not recommended. Keep from freezing.

CONTAINER DISPOSAL: Nonrefillable Container.

{Text for nonrefillable containers that are 5 gallons or smaller}

Do not reuse or refill this container. Offer for recycling if available. Offer for reconditioning if appropriate. Triple rinse container or equivalent, promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for ten seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

CONTAINER DISPOSAL: Nonrefillable Container.

{Text for nonrefillable containers that are larger than 5 gallons}

Do not reuse or refill this container. Offer for recycling if available. Offer for reconditioning if appropriate. Triple rinse container, or equivalent, promptly after emptying.

Triple rinse as follows: Empty remaining contents into application equipment or mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip the container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this process two more times.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: CAUTION: Harmful if swallowed. Harmful if inhaled. Avoid breathing vapor or spray mist. Causes moderate eye irritation. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or going to the restroom.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

FIRST AID	
<i>If inhaled</i>	<ul style="list-style-type: none">- Move person to fresh air.- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.- Call a poison control center or doctor for further treatment advice.
<i>If on skin</i>	<ul style="list-style-type: none">- Take off contaminated clothing.- Rinse skin immediately with plenty of water for 15-20 minutes.- Call a poison control center or doctor for treatment advice.
<i>If eyes</i>	<ul style="list-style-type: none">- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes, then continue rinsing eye.- Call a poison control center or doctor for treatment advice.
<i>If swallowed</i>	<ul style="list-style-type: none">- Call a poison control center or doctor immediately for treatment advice.- Have person sip a glass of water if able to swallow.- Do not induce vomiting unless told to do so by a poison control center or doctor.- Do not give anything by mouth to an unconscious person.
	<ul style="list-style-type: none">- Have the product container or label with you when calling a poison control center or doctor or going for treatment.- For emergency information on this product, call National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT) seven days a week. During other times, call the poison control center 1-800-222-1222

USE INFORMATION

Purogene® is an effective disinfectant against the following human pathogens of significant public health interest when used according to label instructions at 500 ppm activated use solution with a ten-minute contact time.

Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)
Poliovirus type 1 (ATCC VR-1562, Strain Chat)

EMERGING VIRAL PATHOGEN CLAIM

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	Poliovirus type 1 (ATCC VR-1562, Strain Chat)
Large, non-enveloped virus	Poliovirus type 1 (ATCC VR-1562, Strain Chat)

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus Type 1 on hard non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus Type 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information."